March of Dimes
Saving babies, together

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Testimony on Behalf of the

March of Dimes Birth Defects Foundation

before the Senate Health, Education, Labor and Pensions Committee

Subcommittee on Public Health

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Presented by:

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Good morning Senator Clinton and members of the Subcommittee. I am John Harris, pediatrician, epidemiologist, and Director of the California Birth Defects Monitoring Program. I am here today on behalf of the March of Dimes Birth Defects Foundation which administers the program. Thank you for the opportunity to testify on the importance of investigating possible connections between the environment and human health, specifically on how best to identify factors contributing to birth defects.

As you may know, the March of Dimes is a national voluntary health agency founded in 1938 by President Roosevelt to find a cure for polio. During its first twenty years, the March of Dimes committed funds to research and Foundation grantees were successful in developing a vaccine to prevent polio. For the last 44 years, the mission of the March of Dimes has been to improve the health of children by preventing birth defects and infant mortality through community services, advocacy, research and education.

The California Birth Defects Monitoring Program was created in 1983 in response to the problem of birth defects and an environmental concern about aerial spraying of the pesticide, malathion. Spraying of malathion turned out to pose no human health risk, but the problem of birth defects persists until this day.

Nationwide, birth defects are the leading cause of infant mortality; in fact, 1 in 28 babies is born with a birth defect. This means that one child in every classroom in America will themselves have a child with a birth defect. Birth defects are serious conditions like spina bifida, cleft lip and palate, Down's syndrome, congenital heart disease, and mental

retardation which often result in disability, multiple hospitalizations, and even death. In California, the CBDMP has estimated that the cost of health care and special education for children with only 18 selected birth defects is over $8 billion per year in 1992 dollars. Most people think that birth defects only happen to the poor, the uneducated, older mothers and teenage mothers. However, this is untrue. California Birth Defects Monitoring Program data demonstrates that birth defects in the aggregate occur with similar frequency across all socioeconomic, racial and maternal age groups. Unfortunately, though birth defects are common, the causes of at least two-thirds of birth defects remain unknown.

Environmental substances that cause reproductive hazards are of concern to the March of Dimes because of their adverse effect on fertility, the outcome of pregnancy, and the health of future generations. When I speak of environment, I am using the broad definition, meaning any chemical, nutritional, infectious, lifestyle, or other exogenous factors. The California Birth Defects Monitoring Program has recently completed a study showing that air pollution from car exhaust is linked to congenital heart disease. On behalf of the March of Dimes, I welcome the opportunity to appear today to urge you to support more surveillance and research to improve our only rudimentary understanding of the relationship between birth defects and the environment.

During the last Congress, the March of Dimes led the advocacy effort to create the National Center on Birth Defects and Developmental Disabilities at the CDC to increase the federal government's involvement in research related to birth defects. This Center,

which began operating in April 2001, is now funding cooperative agreements in 28 states and territories to initiate or improve state birth defects monitoring programs. These cooperative agreements are typically funded for a three-year period with annual support varying from $100,000 to $200,000 for each project. Regrettably, this year, the federal appropriations amount was insufficient to fund all the states that applied for assistance. The March of Dimes would like to see all states receive funding and at higher average level. Increasing funding for these cooperative agreements from the current level of $4.1 million to $7. 5 would allow CDC to fund the additional states which applied in 2001 but which could not be funded because of insufficient resources. Additional funds would also allow CDC to increase the amount of individual state awards. These state surveillance programs are vitally important because they collect data that are used to detect trends in birth defects and point the way for further research. State birth defects surveillance programs are also used by states to link children with birth defects to needed services.

In addition to the cooperative agreements, CDC is currently funding 8 regional Centers for Birth Defects Research and Prevention. These 8 Centers – which include the California Birth Defects Monitoring Program – have been funded for five years and are located in state health departments or university medical schools and one is run by the CDC. These Centers were established in states with existing birth defect programs that had nationally recognized expertise in birth defects surveillance and research. Each center receives approximately $900,000 per year from CDC. Researchers at each of these Centers examine the effects of genetics and the environment on birth defects.

The eight regional Centers are collaborating on the largest study ever undertaken on the causes of human birth defects, the National Birth Defects Prevention Study. This unique research project has been up and running for five years. Each center conducts at least 300 interviews per year, resulting in a pooled database of 12,000 interviews. The study involves:

- Identifying infants with major birth defects,
- Interviewing mothers about their medical history, environmental exposures, and lifestyle,
- Collecting cheek swabs from infants and parents to study gene-environment interactions,
- Establishing a specimen bank to store biologic samples for future study.

With increased funding, these Centers could collect additional information that would allow for the study of genetic and environmental causes of birth defects and thereby increase dramatically our understanding of key underlying factors that may cause birth defects. The March of Dimes recommends increasing funding for the work done by these Centers by $6 million (to a total of $12 million). This funding for surveillance and research will facilitate the development of effective programs to prevent the tragedy of birth defects which occur among 150,000 American families every year.

Adding resources to this study will provide a national source of information on potential causes of birth defects and, over time, will generate data critical to identifying substances in our environment that are harmful to developing fetuses. This collaborative study will enable scientists to study the epidemiology of some rare birth defects for the first time,

and the compiled data and banked DNA will facilitate future research as new hypotheses and improved technologies emerge.

Let me cite an example from our research in California that will demonstrate the importance of investigating genetic/environment interaction. The California Birth Defects Monitoring Program has found that smoking, together with a genetic factor, results in an eight-fold increase in the risk of cleft lip and palate. The specific genetic factor (TGF alpha variant) is harmless by itself and is found in 14% of babies. As a general rule, genetic risk factors by themselves do not cause birth defects. To be harmful, they need to be triggered by an environmental factor. Let me give you an analogy for thinking about genetic/environment interactions. Think of genes as a windy road – by itself harmless. Think of an environmental factor as driving an automobile at a speed of 80 miles per hour. The combination of a windy road and going 80 miles per hour can be lethal.

So why double the funding of the 8 birth defects research centers currently supported by the CDC? First, every child deserves a healthy start in life. Second, if this research is not funded, the American public will continue to spend many times more on treatment and special education. An ounce of birth defects prevention is truly worth a ton of cure. And the third reason is more personal. I told you that in every classroom in America one of those children will themselves have a child with a serious birth defect. Who will be the 1 in 28? Perhaps she will be one of your friends. Perhaps he will be my son, Evan, who is

now 21 or my daughter, Sasha, who will turn 18 next month. Or perhaps she will be a Senator's, a C.E.O's, or a President's daughter.

So I leave you with one final thought. Why not set us on a path to prevent birth defects by approving a modest $10 million increase in funding for state tracking and for these research Centers? The March of Dimes urges you to make this investment in birth defects surveillance, research and prevention a legislative priority for this Congress. Thank you.